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**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

HOSPIRA, INC. and ORION
CORPORATION,

Plaintiffs,

v.

SANDOZ INTERNATIONAL GmbH and
SANDOZ INC.,

Defendants.

Civil Action No. 3:09-cv-04591-MLC-TJB

Filing Date: September 4, 2009

Judge Mary L. Cooper

**SANDOZ INC.'S ANSWER, AFFIRMATIVE DEFENSES, COUNTERCLAIMS TO
PLAINTIFFS' COMPLAINT AND DEMAND FOR JURY TRIAL**

Defendant Sandoz Inc. ("Sandoz"), by and through its undersigned attorneys, hereby answers each of the numbered paragraphs of the Complaint filed on September 4, 2009 by Hospira, Inc. ("Hospira") and Orion Corp. ("Orion") (collectively "Plaintiffs"). Except as expressly admitted below, Sandoz denies each allegation of the Plaintiffs' Complaint.

PARTIES

1. Sandoz admits the allegations of Paragraph 1.
2. Sandoz admits that Orion is a corporation with its principal place of business at Orionintie 1A, FI-02200 Espoo, Finland. Sandoz lacks knowledge or information sufficient to

form a belief as to the truth of the remaining allegations in Paragraph 2 and therefore denies them.

3. Sandoz admits that Sandoz International GmbH is a German corporation. Sandoz denies that Sandoz International GmbH has a principal place of business at Industriestrasse 25, Holzkirchen 83607, Germany.

4. Sandoz admits the allegations of Paragraph 4.

5. Sandoz denies the allegations of Paragraph 5.

6. Sandoz denies the allegations of Paragraph 6.

7. Sandoz denies the allegations of Paragraph 7.

8. Sandoz denies the allegations of Paragraph 8.

9. The allegations in Paragraph 9 are directed to another Defendant and therefore require no response from Sandoz. *See* Fed. R. Civ. P. 8(b)(1)(B). To the extent that a response is required, Sandoz objects that the allegations in Paragraph 9 are not “simple, concise, and direct” as required under Federal Rule of Civil Procedure 8(d)(1) and, on that basis, denies the allegations of Paragraph 9. To the extent that a response is nevertheless required despite Sandoz’s objection, Sandoz denies the allegations of Paragraph 9.

NATURE OF THE ACTION

10. Sandoz admits that this is a civil action involving U.S. Patent Nos. 4,910,214 (“the ’214 patent”) and 6,716,867 (“the ’867 patent”).

11. Sandoz admits that this action is based upon the United States patent laws, 35 U.S.C. § 1 *et seq.* Sandoz admits that this action relates to an Abbreviated New Drug Application (“ANDA”) seeking approval to sell Dexmedetomidine Hydrochloride Injection 100 mcg base/ml prior to the expiration of the ’214 and ’867 patents, which are listed in the Orange

Book in connection with the proprietary name PRECEDEX. Sandoz denies the remaining allegations of Paragraph 11.

JURISDICTION AND VENUE

12. Sandoz admits the allegation of Paragraph 12.

13. Sandoz admits the allegation of Paragraph 13.

14. Sandoz admits that it is subject to personal jurisdiction in this District.

15. The allegations in Paragraph 15 are directed to another Defendant and therefore require no response from Sandoz. *See* Fed. R. Civ. P. 8(b)(1)(B). To the extent that a response is required, Sandoz denies the allegations of Paragraph 15.

16. Sandoz admits that venue is proper in this District.

THE PATENTS-IN-SUIT

17. Sandoz admits that the '214 patent is entitled "Optical Isomer of an Imidazole Derivative Medetomidine as an Alpha-2-Receptor Agonist" and issued on March 20, 1990. Sandoz denies that the '214 patent was duly and legally issued by the United States Patent and Trademark Office ("PTO"). Sandoz lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in Paragraph 17 and therefore denies them.

18. Sandoz lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 18 and therefore denies them.

19. Sandoz admits that the '867 patent is entitled "Use of Dexmedetomidine for ICU Sedation" and issued on April 6, 2004. Sandoz denies that the '867 patent was duly and legally issued by the PTO. Sandoz lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in Paragraph 19 and therefore denies them.

20. Sandoz lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 20 and therefore denies them.

21. Sandoz admits that New Drug Application No. 021038 was approved on December 17, 1999, and lists Hospira as the Company, Dexmedetomidine as the Active Ingredient, 100 ugm base/mL as the Strength, injection as the Dosage Form, and PRECEDEX as the proprietary Drug Name.

22. Sandoz admits that the '214 and '867 patents are listed in the Orange Book in connection with the proprietary Drug Name PRECEDEX. Sandoz denies that the claims of the '214 and/or '867 patents cover PRECEDEX or any formulations or methods of use thereof.

ACTS GIVING RISE TO THIS ACTION

23. Sandoz admits the allegations of Paragraph 23 that are directed to Sandoz. To the extent that the allegations in Paragraph 23 are directed to another Defendant, Sandoz lacks knowledge or information sufficient to form a belief about the truth of such allegations and therefore denies them.

24. Sandoz admits the allegations of Paragraph 24 that are directed to Sandoz. To the extent that the allegations in Paragraph 24 are directed to another Defendant, Sandoz lacks knowledge or information sufficient to form a belief about the truth of such allegations and therefore denies them.

25. Sandoz admits the allegations of Paragraph 25.

26. Sandoz admits the allegations of Paragraph 26.

27. Sandoz admits the allegations of Paragraph 27.

28. Sandoz admits the allegations of Paragraph 28.

29. Sandoz denies the allegations of Paragraph 29 that are directed to Sandoz. To the extent that the allegations in Paragraph 29 are directed to another Defendant, such allegations require no response from Sandoz. *See* Fed. R. Civ. P. 8(b)(1)(B). To the extent that a response to allegations against another Defendant is required, Sandoz denies such allegations.

30. Sandoz admits that it was aware of the patents-in-suit when it filed ANDA No. 91-465 containing a Paragraph IV certification. To the extent that the allegations in Paragraph 30 are directed to another Defendant, such allegations require no response from Sandoz. *See* Fed. R. Civ. P. 8(b)(1)(B). To the extent that a response to allegations against another Defendant is required, Sandoz lacks knowledge or information sufficient to form a belief about the truth of such allegations and therefore denies them.

31. Sandoz admits that this action was commenced within 45 days of the July 27, 2009 notice letter and Paragraph IV certification. Sandoz lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations of Paragraph 31 and therefore denies them.

FIRST CLAIM FOR RELIEF

(Infringement of the '214 Patent by Defendants)

32. Sandoz admits that Plaintiffs incorporated Paragraphs 1 through 31 as previously set forth in the Complaint.

33. Sandoz admits that its submission of ANDA No. 91-465 with a Paragraph IV certification under Section 505(j) of the Food, Drug, and Cosmetic Act ("FDCA") constitutes only a statutory act of infringement of the '214 patent under 35 U.S.C. § 271(e)(2)(A).

34. Sandoz denies the allegations of Paragraph 34 that are directed to Sandoz. To the extent that the allegations in Paragraph 34 are directed to another Defendant, such allegations

require no response from Sandoz. *See* Fed. R. Civ. P. 8(b)(1)(B). To the extent that a response to allegations against another Defendant is required, Sandoz denies such allegations.

35. Sandoz admits knowledge of the '214 patent prior to filing ANDA No. 91-465, and admits knowledge that filing the ANDA and its accompanying Paragraph IV certification would constitute only a statutory act of infringement under 35 U.S.C. § 271(e)(2)(A). Except as expressly admitted, Sandoz denies the remaining allegations of Paragraph 35 that are directed to Sandoz. To the extent that the allegations in Paragraph 35 are directed to another Defendant, such allegations require no response from Sandoz. *See* Fed. R. Civ. P. 8(b)(1)(B). To the extent that a response to allegations against another Defendant is required, Sandoz lacks knowledge or information sufficient to form a belief about the truth of such allegations and therefore denies them.

36. Sandoz denies the allegations of Paragraph 36.

SECOND CLAIM FOR RELIEF

(Infringement of the '867 Patent by Defendants)

37. Sandoz admits that Plaintiffs incorporated Paragraphs 1 through 36 as previously set forth in the Complaint.

38. Sandoz admits that its submission of ANDA No. 91-465 with a Paragraph IV certification under Section 505(j) of the FDCA constitutes only a statutory act of infringement of the '867 patent under 35 U.S.C. § 271(e)(2)(A).

39. Sandoz denies the allegations of Paragraph 39 that are directed to Sandoz. To the extent that the allegations in Paragraph 39 are directed to another Defendant, such allegations require no response from Sandoz. *See* Fed. R. Civ. P. 8(b)(1)(B). To the extent that a response to allegations against another Defendant is required, Sandoz denies such allegations.

40. Sandoz denies the allegations of Paragraph 40 that are directed to Sandoz. To the extent that the allegations in Paragraph 40 are directed to another Defendant, such allegations require no response from Sandoz. *See* Fed. R. Civ. P. 8(b)(1)(B). To the extent that a response to allegations against another Defendant is required, Sandoz denies such allegations.

41. Sandoz admits knowledge of the '867 patent prior to filing ANDA No. 91-465, and admits knowledge that filing that ANDA and its accompanying Paragraph IV certification would constitute only a statutory act of infringement under 35 U.S.C. § 271(e)(2)(A). Except as expressly admitted, Sandoz denies the remaining allegations of Paragraph 41 that are directed to Sandoz. To the extent that the allegations in Paragraph 41 are directed to another Defendant, such allegations require no response from Sandoz. *See* Fed. R. Civ. P. 8(b)(1)(B). To the extent that a response to allegations against another Defendant is required, Sandoz lacks knowledge or information sufficient to form a belief about the truth of such allegations and therefore denies them.

42. Sandoz denies the allegations of Paragraph 42 that are directed to Sandoz. To the extent that the allegations in Paragraph 42 are directed to another Defendant, such allegations require no response from Sandoz. *See* Fed. R. Civ. P. 8(b)(1)(B). To the extent that a response to allegations against another Defendant is required, Sandoz denies such allegations.

THIRD CLAIM FOR RELIEF

(Inducement of Infringement of the Patents-in-Suit by Sandoz International GmbH)

43. Sandoz admits that Plaintiffs incorporated Paragraphs 1 through 42 as previously set forth in the Complaint.

44. Sandoz denies the allegations of Paragraph 44 that are directed to Sandoz. To the extent that the allegations in Paragraph 44 are directed to another Defendant, such allegations

require no response from Sandoz. *See* Fed. R. Civ. P. 8(b)(1)(B). To the extent that a response to allegations against another Defendant is required, Sandoz denies such allegations.

45. Sandoz denies the allegations of Paragraph 45 that are directed to Sandoz. To the extent that the allegations in Paragraph 45 are directed to another Defendant, such allegations require no response from Sandoz. *See* Fed. R. Civ. P. 8(b)(1)(B). To the extent that a response to allegations against another Defendant is required, Sandoz denies such allegations.

46. Sandoz denies the allegations of Paragraph 46 that are directed to Sandoz. To the extent that the allegations in Paragraph 46 are directed to another Defendant, such allegations require no response from Sandoz. *See* Fed. R. Civ. P. 8(b)(1)(B). To the extent that a response to allegations against another Defendant is required, Sandoz denies such allegations.

47. Sandoz denies the allegations of Paragraph 47 that are directed to Sandoz. To the extent that the allegations in Paragraph 47 are directed to another Defendant, such allegations require no response from Sandoz. *See* Fed. R. Civ. P. 8(b)(1)(B). To the extent that a response to allegations against another Defendant is required, Sandoz denies such allegations.

AFFIRMATIVE DEFENSES

Without admitting or implying that Sandoz bears the burden of proof as to any of them, Sandoz asserts, on information and belief, the following affirmative defenses:

FIRST AFFIRMATIVE DEFENSE

(Failure to State a Claim)

1. The Complaint fails to state a claim upon which relief can be granted.

SECOND AFFIRMATIVE DEFENSE

(Noninfringement of the '214 Patent)

2. Sandoz has not infringed, induced infringement of, or contributed to the infringement of any claim of the '214 patent because when properly interpreted the claims of the '214 patent do not describe or encompass, either literally or by equivalents, any product made, used, offered for sale, or sold by Sandoz; nor any product that Sandoz induces others to make, use, or sell; nor any product to which Sandoz contributes to the making, using, or selling; nor any product for which Sandoz has filed an ANDA.

THIRD AFFIRMATIVE DEFENSE

(Invalidity of the '214 Patent)

3. The '214 patent, and each claim thereof, is invalid for failing to comply with the requirements of the patent laws of the United States, particularly with regard to one or more of the requirements specified in Sections 101, 102, 103, and/or 112 of Title 35 of the United States Code.

FOURTH AFFIRMATIVE DEFENSE

(Inequitable Conduct During Prosecution of the '214 Patent)

4. The '214 patent is unenforceable as a result of inequitable conduct during prosecution before the PTO, as more particularly explained and alleged in the Third Counterclaim.

FIFTH AFFIRMATIVE DEFENSE

(Noninfringement of the '867 Patent)

5. Sandoz has not infringed, induced infringement of, or contributed to the infringement of any claim of the '867 patent because when properly interpreted the claims of the '867 patent do not describe or encompass, either literally or by equivalents, any product made, used, offered for sale, or sold by Sandoz; nor any product that Sandoz induces others to make,

use, or sell; nor any product to which Sandoz contributes to the making, using, or selling; nor any product for which Sandoz has filed an ANDA.

SIXTH AFFIRMATIVE DEFENSE

(Invalidity of the '867 Patent)

6. The '867 patent, and each claim thereof, is invalid for failing to comply with the requirements of the patent laws of the United States, particularly with regard to one or more of the requirements specified in Sections 101, 102, 103, and/or 112 of Title 35 of the United States Code.

SEVENTH AFFIRMATIVE DEFENSE

(Inequitable Conduct During Prosecution of the '867 Patent)

7. The '867 patent is unenforceable as a result of inequitable conduct during prosecution before the PTO, as more particularly explained and alleged in the Sixth Counterclaim below.

EIGHTH AFFIRMATIVE DEFENSE

(Unclean Hands)

8. The patents-in-suit are unenforceable under the doctrine of unclean hands.

NINTH AFFIRMATIVE DEFENSE

(Miscellaneous Reservation of Rights)

9. Sandoz presently asserts the above defenses without the benefit of full discovery and investigation, and reserves the right to supplement or amend these affirmative defenses as necessary.

COUNTERCLAIMS

Defendant and Counterclaimant Sandoz hereby submits these Counterclaims against Hospira and Orion (“Plaintiffs”):

JURISDICTION AND VENUE

1. The Court has subject matter jurisdiction over these Counterclaims under the provisions of 28 U.S.C. § 1331, 1338(a), and 1367(a).

2. Venue in this district is also proper pursuant to 28 U.S.C. § 1391(b) and (c) in that Plaintiffs are subject to the personal jurisdiction of this Court by commencing and continuing to prosecute this action; because a substantial part of the events giving rise to Sandoz’s counterclaims occurred in this district; and each Counterdefendant is found or transacts business in this judicial district.

FIRST COUNTERCLAIM

(Declaratory Judgment of Noninfringement of the ’214 Patent)

3. Sandoz hereby incorporates by reference each and every allegation set forth in paragraphs 1 through 47 of its Answer, 1 through 9 of its Affirmative Defenses, and 1 through 2 of these Counterclaims above.

4. Sandoz and its Dexmedetomidine Hydrochloride Injection 100 mcg base/ml product (the “Sandoz product”) do not infringe the ’214 patent, directly or indirectly, either literally or by the doctrine of equivalents.

5. There exists an actual controversy between Sandoz and Plaintiffs regarding whether Sandoz infringes the ’214 patent, and a judicial declaration of noninfringement is necessary and appropriate at this time.

SECOND COUNTERCLAIM

(Declaratory Judgment of Invalidity of the '214 Patent)

6. Sandoz hereby incorporates by reference each and every allegation set forth in Paragraphs 1 through 47 of the Answer, 1 through 9 of the Affirmative Defenses, and 1 through 5 of these Counterclaims above.

7. The '214 patent, and each claim thereof, is invalid for failing to comply with the requirements of the patent laws of the United States, particularly with regard to one or more of the requirements specified in Sections 101, 102, 103, and/or 112 of Title 35 of the United States Code.

8. There exists an actual controversy between Sandoz and Plaintiffs regarding the validity of the '214 patent, and a judicial declaration of invalidity is necessary and appropriate at this time.

THIRD COUNTERCLAIM

(Declaratory Judgment of Unenforceability of the '214 Patent)

9. Sandoz hereby incorporates by reference each and every allegation set forth in Paragraphs 1 through 47 of the Answer, 1 through 9 of the Affirmative Defenses, and 1 through 8 of these Counterclaims above.

10. The '214 patent is unenforceable due to Plaintiffs' unclean hands.

11. The '214 patent is unenforceable as a result of inequitable conduct during prosecution before the PTO, as more particularly explained and alleged below.

12. The '214 patent is directed to dexmedetomidine, the *d*-enantiomer of medetomidine, which is an α_2 -adrenergic receptor agonist. The '214 patent alleges that the *d*-enantiomer possesses highly enhanced α_2 -selectivity and potency compared to the racemic

mixture of medetomidine, which contains equal amounts of both the *d*-enantiomer and *l*-enantiomer. '214 patent col. 2 ll.20-30.

13. The originally filed claims of the '214 patent application were directed to, *inter alia*, the enantiomers of medetomidine and methods for separating them.

14. In an Office Action mailed March 17, 1989, the PTO rejected several of these claims as obvious in view of the prior art. The Examiner reasoned that it would have been obvious to separate racemic medetomidine into its enantiomers because it was known in the art that one enantiomer is typically more active than the other.

15. In their Amendment and Remarks filed September 18, 1989, the Applicants for the '214 patent canceled claims directed to the *l*-enantiomer and the method for separating the enantiomers. To overcome the obviousness rejection and obtain allowance of the remaining claims directed to the *d*-enantiomer of medetomidine, the Applicants emphasized the unexpected results allegedly achieved by the *d*-enantiomer. Specifically, Applicants presented certain “selectivity data” purportedly demonstrating the “surprising activity” of the *d*-enantiomer with respect to its α_2 - α_1 -selectivity ratio. The Applicants represented that the *d*-enantiomer had a much greater selectivity for the α_2 -adrenergic receptor over the α_1 -adrenergic receptor that they represented was “more than nine times that of the racemate.” According to the Applicants, “[t]his advantageous effect is completely unexpected and could not be predicted.” A Notice of Allowance was subsequently issued as a result of these assertions.

16. The Applicants' representation of unexpected results was based on the specific data in Table 2 of the '214 patent, which purportedly shows, among other things, that the α_2/α_1 selectivity for the *d*-enantiomer (45849) is more than nine times greater than that for racemic medetomidine (5060). The data in Table 2 of the '214 patent was generated and published by

one of the inventors, Raimo E. Virtanen and a colleague in 1985. *See* Eur. J. Pharmac. 108: 163-69 (1985) (“Virtanen 1985 report”).

17. During prosecution of the '214 patent, the Applicants knew or should have known that the selectivity data in Table 2 was inaccurate, generated by inferior experimental methods, and/or contrary to the scientific understanding in the art.

18. The data in Table 2 purportedly demonstrate synergy between the *d*- and *l*-enantiomers when binding to the α_1 -adrenergic receptor. According to the data in the center column of Table 2, the affinity of the *l*-enantiomer is 10-fold that of racemic medetomidine, and the affinity of the *d*-enantiomer is 3.5 fold greater, suggesting synergistic binding by both enantiomers at separate sites on the α_1 -adrenergic receptor. However, such a conclusion was contrary to the accepted model and understanding of α_1 -adrenergic receptor activation at that time (and now), which contemplated only a single binding site. This disconnect between the experimental data and the scientific understanding of the α_1 -adrenergic receptor would have alerted one skilled in the art to question the accuracy and integrity of the data in Table 2, and avoid drawing conclusions from such questionable data. Instead, however, Applicants affirmatively relied on that data in alleging unexpected results to obtain allowance of the '214 patent.

19. Similarly, the Applicants, including at least Virtanen, knew or should have known that the data in Table 2 was questionable at least with regard to medetomidine because subsequent work by Virtanen produced a different selectivity ratio for medetomidine of 1620 rather than the 5060 reported in Table 2 of the '214 patent. *See* Virtanen, R. *et al.*, Eur. J. Pharmac. 150:9-14 (1988) (“Virtanen 1988 report”). The Virtanen 1988 report was submitted and accepted for publication prior to the filing date of the '214 patent application.

20. Virtanen also knew or should have known that the data in the Virtanen 1985 report and Table 2 was obtained using an inferior receptor binding assay whose shortcomings undermined the accuracy of the selectivity data. Virtanen's own subsequent 1988 report employed a superior receptor binding assay that was substantially improved in several respects, including changes to the method by which nonspecific binding was defined, the amount of radioligand used, buffer pH levels, specific amounts of tissue used, and assay wash protocols. Virtanen's own extensive methodological modifications and improvements demonstrate his personal awareness that the earlier data from the Virtanen 1985 report and Table 2 were inaccurate.

21. As a co-inventor, Virtanen signed an Inventor's Declaration stating that he would disclose all information known to him to be material to patentability, and had an ongoing duty to disclose material information to the PTO throughout the entire prosecution of the '214 patent. Yet at no point did Virtanen or Applicants ever cite, disclose, or otherwise call the Examiner's attention to the discrepancies and shortcomings in the experimental data and methods that were relied upon in alleging unexpected results to overcome the Examiner's obviousness rejections. The questionable nature of the experimental data and methods of Table 2 were never disclosed, were not cumulative to any information already of record during prosecution, and would have refuted or been inconsistent with the Applicants' position regarding unexpected results and nonobviousness. The information was material to patentability, and a reasonable examiner would have considered this information important when deciding whether to allow the '214 patent.

22. Despite the relevance and materiality of the above information, the Applicants intentionally withheld this information from the PTO, because its disclosure would have

undermined their position regarding unexpected results that was central to obtaining allowance of the '214 patent. A deliberate intent to deceive may be inferred from these facts.

23. Withholding the Virtanen 1988 report and relying on the inaccurate 1985 data in Table 2 was also a misrepresentation that was intended to deceive the PTO regarding unexpected results.

24. Because Virtanen was an investigator and author of both studies, there is no credible good-faith explanation based on mistake, inadvertence, or otherwise for the nondisclosure of the 1988 report and/or the inaccurate nature of the 1985 data in Table 2.

25. Virtanen's inequitable conduct was committed as part of a successful attempt to convince the Examiner of unexpected results achieved by the *d*-enantiomer of medetomidine. Because the "*d*-enantiomer" is a limitation recited in every issued claim of the '214 patent, every claim of the '214 patent was tainted by Virtanen's nondisclosure and misrepresentation.

26. The nondisclosure and misrepresentation described above was a breach of the duty of candor owed to the PTO, and constitutes inequitable conduct that renders all claims of the '214 patent unenforceable.

27. Sandoz reserves the right to further supplement or amend these allegations as more information becomes available through discovery.

28. There exists an actual controversy between Sandoz and Plaintiffs regarding the enforceability of the '214 patent, and a judicial declaration of unenforceability is necessary and appropriate at this time.

FOURTH COUNTERCLAIM

(Declaratory Judgment of Noninfringement of the '867 Patent)

29. Sandoz hereby incorporates by reference each and every allegation set forth in paragraphs 1 through 47 of its Answer, 1 through 9 of its Affirmative Defenses, and 1 through 28 of these Counterclaims above.

30. Sandoz and its Dexmedetomidine Hydrochloride Injection 100 mcg base/ml product (the "Sandoz product") do not infringe the '867 patent, directly or indirectly, either literally or by the doctrine of equivalents.

31. There exists an actual controversy between Sandoz and Plaintiffs regarding whether Sandoz infringes the '867 patent, and a judicial declaration of noninfringement is necessary and appropriate at this time.

FIFTH COUNTERCLAIM

(Declaratory Judgment of Invalidity of the '867 Patent)

32. Sandoz hereby incorporates by reference each and every allegation set forth in Paragraphs 1 through 47 of the Answer, 1 through 9 of the Affirmative Defenses, and 1 through 31 of these Counterclaims above.

33. The '867 patent, and each claim thereof, is invalid for failing to comply with the requirements of the patent laws of the United States, particularly with regard to one or more of the requirements specified in Sections 101, 102, 103, and/or 112 of Title 35 of the United States Code.

34. There exists an actual controversy between Sandoz and Plaintiffs regarding the validity of the '867 patent, and a judicial declaration of invalidity is necessary and appropriate at this time.

SIXTH COUNTERCLAIM

(Declaratory Judgment of Unenforceability of the '867 Patent)

35. Sandoz hereby incorporates by reference each and every allegation set forth in Paragraphs 1 through 47 of the Answer, 1 through 9 of the Affirmative Defenses, and 1 through 34 of these Counterclaims above.

36. The '867 patent is unenforceable due to Plaintiffs' unclean hands.

37. The '867 patent is unenforceable as a result of inequitable conduct during prosecution before the PTO, as more particularly explained and alleged below.

38. The '867 patent is directed to a method of sedating a patient in an intensive care unit by the administration of dexmedetomidine (the *d*-enantiomer of medetomidine), wherein the patient remains arousable and oriented.

39. In 1993, five years prior to the '867 patent filing date, a co-inventor named Riku Aantaa co-authored a scientific literature review comparing dexmedetomidine to clonidine, and concluded that the two compounds were equivalent. *See* Aantaa, R. and Scheinin, M., *Acta Anesth. Scand.* 37: 433-48 (1993) ("the Aantaa review"). The Aantaa review states at page 437 that "[t]he pharmacological actions of dexmedetomidine . . . closely resemble those of clonidine." The Aantaa review also cites at page 435 various publications similarly concluding that the two drugs acted at the same site of action on their target receptor, and likewise states at Page 442 that the effects of dexmedetomidine "closely resemble those induced by clonidine."

40. None of these statements equating dexmedetomidine and clonidine were ever disclosed to the PTO during prosecution, even though the Aantaa review was published five years prior to the filing date of the '867 patent.

41. The Applicants, including Aantaa, instead adopted the exact opposite position during prosecution of the '867 patent, asserting that dexmedetomidine was unique and unlike other sedatives. Specifically, the '867 patent states that the applicants "have surprisingly discovered" that dexmedetomidine is an ideal agent for sedation and patient comfort, and that the "quality of sedation" is "unique" because patients sedated by dexmedetomidine remained "arousable and oriented" thus making their treatment easier. '867 patent, col. 4 ll.30-55.

42. The Applicants relied on this characterization during prosecution to demonstrate unexpected results in responding to an obviousness rejection in an August 9, 2002 submission to the PTO, noting that dexmedetomidine "produces an unexpected quality of sedation not achieved by other ICU sedatives" because "[p]atients are asleep but easily arousable and well-oriented" Later during examination, the Applicants amended the independent claims to specifically recite the limitation "wherein the patient remains arousable and orientated" and also continued to assert unexpected results for dexmedetomidine. The obviousness rejections were subsequently withdrawn and the application issued as the '867 patent.

43. Aantaa signed an Inventor's Declaration stating that he would disclose all information known to him to be material to patentability. As the author of his own prior literature review, Aantaa was aware or should have been aware that his prior work directly refuted the positions being taken during prosecution.

44. As a co-inventor, Aantaa had an ongoing duty to disclose material information to the PTO throughout prosecution of the '867 patent. However, he never cited, disclosed, or otherwise called the Examiner's attention to his own prior contrary statements comparing and equating dexmedetomidine and clonidine. The Aantaa review was not cumulative to information already of record, and would have refuted or been inconsistent with the Applicants'

position that dexmedetomidine had achieved unique and unexpected results as a sedative. A reasonable examiner would have considered the prior contrary statements of a co-inventor important in deciding whether to allow the '867 patent.

45. Despite the relevance and materiality of his own prior work, Aantaa intentionally failed to disclose and withheld from the PTO his own publication because that information would have undermined the patentability of the claimed invention. A deliberate intent to deceive may be inferred from these facts.

46. Withholding the prior inconsistent statements in the Aantaa review and relying on inaccurate characterizations regarding the unique and unexpected activity of dexmedetomidine was also a misrepresentation intended to deceive the PTO and obtain allowance of the '867 patent.

47. There is no credible good-faith explanation based on mistake, inadvertence, or otherwise for the nondisclosure of the Aantaa review, whose nondisclosure instead reflected an intentional effort to deceive the PTO.

48. Because each claim recites the limitation "arousable and orientated," and those attributes were relied upon in establishing unexpected results during prosecution, the nondisclosure of the Aantaa review tainted the issuance of every claim in the '867 patent.

49. By intentionally withholding and misrepresenting material information and relying on that deception to obtain allowance of the '867 patent in the manner described above, the Applicants, including at least Aantaa, breached the duty of candor owed to the PTO and committed inequitable conduct that renders all claims of the '867 patent unenforceable.

50. Sandoz reserves the right to further supplement or amend these allegations as more information becomes available through discovery.

51. There exists an actual controversy between Sandoz and Plaintiffs regarding the enforceability of the '867 patent, and a judicial declaration of unenforceability is necessary and appropriate at this time.

PRAYER FOR RELIEF

WHEREFORE, Sandoz asks this Court to enter judgment in its favor and grant the following relief:

1. Dismissing with prejudice the entirety of Plaintiffs' Complaint;
2. Dismissing all remedies and relief sought by Plaintiffs in the Complaint;
3. Declaring that Sandoz has not infringed, and is not infringing, any patent at issue in this case, including the '214 and '867 patents;
4. Declaring that the patents at issue in this case, including the '214 and '867 patents, are invalid, unenforceable, and void in law;
5. Finding this to be an exceptional case and awarding Sandoz its costs, attorneys' fees, and expenses pursuant to 35 U.S.C. § 285; and
6. Granting such other and further relief as the Court may deem just and proper.

JURY DEMAND

Sandoz demands a trial by jury on all issues so triable.

Dated: October 16, 2009

HILL WALLACK LLP

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Attorneys for Defendant
SANDOZ INC.

LOCAL CIVIL RULE 11.2 CERTIFICATION

I hereby certify pursuant to Local Civil Rule 11.2 that to the best of my knowledge, information and belief the patents at issue in this action are not at issue in any other actions.

/s/ Eric I. Abraham

Eric I. Abraham

Dated: October 16, 2009

FED. R. CIV. PRO. 7.1 DISCLOSURE STATEMENT

ERIC I. ABRAHAM, of full age, under oath, hereby declares as follows:

1. I am a member of the Bar of the State of New Jersey and am admitted to practice before the United States District Court for the District of New Jersey.
2. I represent Defendant Sandoz Inc., a corporation organized and existing under the laws of the State of Colorado, having a place of business at 506 Carnegie Center, Princeton, New Jersey 08540.
3. Novartis AG is the ultimate parent company of Sandoz Inc., owning 100% of Sandoz Inc. and trading on the New York Stock Exchange under the ticker symbol NVS.

I declare that the foregoing statements made by me are true. I am aware that if any of the foregoing statements made by me are willfully false, I am subject to punishment.

Executed on October 16, 2009.

/s/ Eric I. Abraham

Eric I. Abraham

CERTIFICATE OF SERVICE

I hereby certify that on October 16, 2009 I served opposing counsel by e-mail and first class U.S. mail, and I electronically filed **SANDOZ INC.'S ANSWER, AFFIRMATIVE DEFENSES, COUNTERCLAIMS TO PLAINTIFFS' COMPLAINT AND DEMAND FOR JURY TRIAL** with the Clerk of Court using the CM/ECF system which will also send notification of such filing to the following:

Agnieszka Antonian
Liza M. Walsh
CONNELL FOLEY LLP
85 Livingston Avenue
Roseland, NJ 07068
Attorneys for Hospira, Inc. and Orion Corp.

I hereby certify that on October 16, 2009, I served opposing counsel by e-mail and first class U.S. mail, a copy of **SANDOZ INC.'S ANSWER, AFFIRMATIVE DEFENSES, COUNTERCLAIMS TO PLAINTIFFS' COMPLAINT AND DEMAND FOR JURY TRIAL** to the following:

Thomas J. Meloro
Colman B. Ragan
Heather M. Schneider
Willkie Farr & Gallagher LLP
787 Seventh Avenue
New York, NY 10019
Attorneys for Hospira, Inc. and Orion Corp.

/s/ Eric I. Abraham _____

Eric I. Abraham